SynZeal Research Pvt Ltd
Plot No. F, Shree Ganesh Industrial Estate,
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Sarkhej-Bavla Road , Moraiya , India-382213
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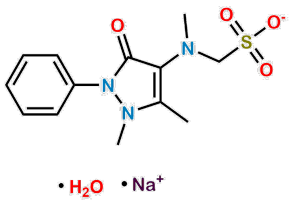
Phone:- +91-757-500-2050

Query ID : SZ-Q-126 **Date :** 1st March 21

Subject: deviation in the area against EPCRS product - around 84% synzeal.

Product Details

Product Name	Metamizole Sodium Monohydrate
CAT No	SZ-M041001
CAS No	5907-38-0
Batch Code	SRLWS-A015
Qty	2500



Query Details

Please be so kind to clarify us the following regarding Metamizole impurity A from our PO 7/21:We performed the RS method of European Pharm. ‘Metamizole Sodium Monohydrate’ 01/2017:1346. The comparable results between imp.A CRS EDQM Vs imp.A SynZeal shows 15.6% deviation. The solutions was injected same date at the same HPLC system and the preparation of solutions performed from the same analyst.Please find below in tabulated form the comparable absorptions from two std’s at C:0.005mg/ml. * data and other records is available in the mail.

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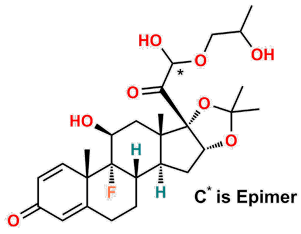
Query ID : SZ-Q-124 **Date :** 23rd February 21

Subject: Rejection of Triamcinolone Acetonide Impurity C PG Hemiacetal

Product Details

Product Name	Triamcinolone Impurity C PG Hemiaceta
CAT No	SZ-T028017
CAS No	2196227-63-9
Batch Code	SRL-404-188
Qty	25



Query Details

Proton NMR observations: According to the Synzeal 21 carbon is CH-OH and 20 carbon is C=O. And According to the Macleods 21 carbon is C=O and 20 carbon is CH-OH. Reasons for this conclusion are elaborated as below, Proton NMR 1) If, 21 Carbon is CH-OH then the proton attached to this carbon shall appears theoretically at about or above 5 ppm because this proton is attached to the two electron withdrawing oxygen atom (HO-CH-OR) 2) Practically this proton appeared at 4.3 ppm indicates that there may not be two oxygen atoms near the 21 CH-OH. 3) In D-exchange the two singlet appeared at about 4.3 ppm indicate the CH-OH group what we predicted is correct. DEPT135: Further due to less sample quantity we performed the DEPT135 and HMQC NMR to confirm the actual structure. 4) If, 21 Carbon is CH-OH then this carbon shall appears theoretically at about or above 100 ppm because this carbon is attached to the two electron withdrawing oxygen atom (HO-CH-OR) 5) Practically this carbon appeared at 73 ppm indicates that there may not be two oxygen atoms near the 21 CH-OH . 6) Based on the literature, intra-molecular cannizaro reaction shall be happened there to form the 20 CH-OH group. 7) If 21 number carbon is CH-OH then the protons attached to the Propylene glycol (O-CH2-) may appeared at about 3.4 ppm but this protons appeared at about 3.9 ppm indicates that ester carbonyl carbon present at 21 position. 8) the signal at about 0.982 ppm (Doublet), 3.1 -3.2 ppm (Multiplet) and 3.5 ppm (Multiplet) Corresponds to the residual propyelene glycol moiety. Based on the above observations we concluded that the Synzeal structure is wrong. and CH-OH group is present at carbon position 20 instead of C21.

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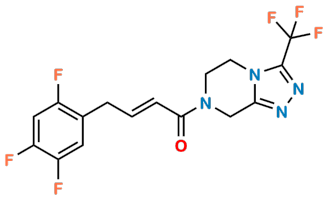
Query ID : SZ-Q-120 **Date :** 10th February 21

Subject: Sitagliptin impurities identification issues [impurity interchange]

Product Details

Product Name	Sitagliptin FP Impurity D
CAT No	SZ-S009008
CAS No	1253056-18-6
Batch Code	SRL-90-96-G
Qty	100



Query Details

A) Injecting impurity C and impurity D from previous suppliers:characteristic UV-Vis spectrum is observed for impurity C, whereas broad spectrum peak is observed for impurity D.As we had no more impurity D from the previous supplier, we opened the vial from Synzeal to continue the method validation.B) Injecting impurity D from Synzeal (batch SRL-90-96-G) together with impurity C from previous supplier, no peak observed at RRT of impurity D. Investigation was carried out and injections were repeated, injecting separately impurity D standards. UV-Vis Spectra was checked and it corresponds to impurity C. As both impurity C and D were purchased from Synzeal, we carried out an investigation to analyze impurity C as well. C) Injecting individually impurity C from Synzeal and previous supplier:Hence, our conclusion is that impurity C and D have been mistakenly identified and cannot be used for validation without an investigation from Synzeal side.- Have been interchanged in the vials? That is, COA for impurity C and D are still available but vials have been mistakenly labelled?- Have been interchanged in the overall identification? That is, CoA for impurity D corresponds to impurity C and vice versa?We ordered 2 vials of 50mg/each for impurity C and other 2 vials of 50mg/each for impurity D. So far, only 1 vial for each impurity has been opened and analyzed.