3.2.P.3.2 Batch Formula

This section contains information regarding the batch formula for Aucta's generic Clobetasol Propionate Foam, 0.05%.

The intended commercial batch size for Clobetasol Propionate Foam, 0.05% is 500 kg, and the composition (%w/w) of commercial batches is exactly the same with the registration batches for all components.

1.0 Overage

No overage of drug substance is used or will be used during the manufacturing process of the exhibit batches or the port-approval commercial batches.

2.0 Formulation used in In Vitro studies

All three registration batches (Lot# 31982, 32595, 32598) were used for comparative in vitro studies with RLD. Table 1 listed the detailed lot information that was used for Clobetasol Propionate Foam in vitro studies.

Table 1 In Vitro Testing Drug Product Lot Information

	Lot Number (packaging Configurations)		
Aucta Product	32595-50g (50g)	31982-100g (100g)	32598-100g (100g)
RLD	MHDK (50g)	MDBK-4 (100g)	NNEN-2 (100g)

The intended commercial batch size for Clobetasol Propionate Foam, 0.05% is 500 kg, and the batch formula is listed in Table 2. The composition (%w/w) of commercial batches is exactly the same with the registration batches for all components.

Table 2 Batch Formula for Aucta's Clobetasol Propionate Foam

Ingredient	% w/w	Theoretical Qty/ Commercial Batch	Qty/ Exhibit Batch #1 31982	Qty/ Exhibit Batch #2 32595	Qty/ Exhibit Batch #3 32598
Dehydrated Alcohol, USP	58.05	290.25 kg	87.070 kg	87.070 kg	87.070 kg
Polysorbate 60, NF	0.41	2.05 kg	615 g	615 g	615 g
Dehydrated Alcohol, USP [2]	1.33	6.65 kg	2.000 kg	2.000 kg	2.000 kg
Cetyl Alcohol, NF	1.14	5.70 kg	1.710 kg	1.710 kg	1.710 kg
Stearyl Alcohol, NF	0.51	2.55 kg	765 g	765 g	765 g
Propylene Glycol, USP	2.09	10.45 kg	3.140 kg	3.140 kg	3.140 kg
Clobetasol Propionate, USP	0.05	250.00 g	75.300 g [1] (theoretical 75.00 g)	75.530 g [1] (theoretical 75.00 g)	75.530 g [1] (theoretical 75.00 g)
Dehydrated Alcohol, USP [2]	1.33	6.65 kg	2.000 kg	2.000 kg	2.000 kg
Purified Water, USP	34.88	174.40 kg	52.30 kg	52.35 kg	52.30 kg
Citric Acid Anhydrous Powder, USP	0.08	0.40 kg	120.000 g	120.000 g	120.000 g
Potassium Citrate Monohydrate Granular, USP	0.13	0.65 kg	195.000 g	195.000 g	195.00 g
Dehydrated Alcohol, USP [3]	n/a [3]	n/a [3]	0.600 kg	0.700 kg	0.750 kg
Total	**100.0**	**500.00 kg**	**150.0 kg**	**150.0 kg**	**150.0 kg**

Filling

	Qty/ Commercial Batch	Qty/ Exhibit Batch #1 (150 k)		Qty/ Exhibit Batch #2 (150 k)		Qty/ Exhibit Batch #3 (150 k)	
		31982-50g	31982-100g	32595-50g	32595-100g	32598-50g	32598-100g
Bulk Product (kg)	500	51.72	97.95	50.89	98.41	46.96	90.71
Theoretical (cans)	Calculated based on the fill size (50 g or 100 g)	994	993	994	993	994	993
Actual (cans)	--	990	922	778 [4]	923	899 [5]	851 [5]

[1] Required amount of API to be dispensed = $\frac{Theoretical\ API\ Quantity\ (kg) \times 100}{\%\ Assay\ Value\ (on\ a\ dry\ basis)}$

[2] For rinsing containers post addition of materials

[3] Use only if required for compensation of alcohol due to evaporation.

[4] Low yield due to the loss associated with sampling and setup adjustment.

[5] Prior to the filling operation of Batch 32598, 12kg of bulk solution was pulled for bulk hold study

Refer to 3.2.R.1.P.1 for Exhibit Batches reconciliation.